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January 13, 2004

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Dockets Management Branch
U.S. Food and Drug Administration
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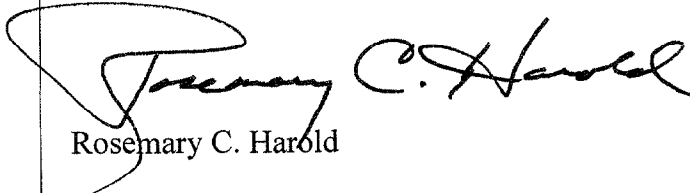
Re: Docket No. 2003N-0344 (Consumer Directed Promotion)

To whom it may concern:

On behalf of Pfizer Inc, the undersigned attorney encloses for filing in the above-referenced docket an original and two copies of reference materials cited in Comments of Pfizer Inc. The Comments of Pfizer Inc. were submitted to the FDA on December 1, 2003.

Should any questions arise concerning this submission, kindly contact the undersigned.

Respectfully submitted,



Rosemary C. Harold

cc: Arnold I. Freide

WRFMAIN 12160479.1

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Books and Publications

1. J. Howard Beales and Timothy J. Muris, *State and Federal Regulation of National Advertising* (1993)
2. Diane C. Berry, et al., *Patients' Understanding of Risk Associated with Medication Use: Impact of European Commission Guidelines and Other Risk Scales*, 26 Drug Safety 1 (2003)
3. George W. Evans & Arnold I. Friede, *The Food and Drug Administration's Regulation of Prescription Drug Manufacturer Speech: A First Amendment Analysis*, 58 Food & Drug L. J. 365 (2003)
4. PhRMA, *The Value of Medicines* (2001)
5. PhRMA, *Why Do Prescription Drugs Cost So Much and Other Questions About Your Medicines* (June 2002)
6. Bert W. Rein et al., Wash. Legal Found., *Proposed Limits on Prescription Drug Ads: A Constitutional Analysis* (July 2002)
7. Meredith B. Rosenthal, Ph.D., et al., Kaiser Family Found., *Demand Effects of Recent Changes in Prescription Drug Promotion* (June 2003)

Newspaper Articles

8. Nat Ives, *The Media Business: Advertising; FDA Ponders Pros And Cons Of The Ways Prescription Drugs Are Promoted To Consumers*, N.Y. Times, Sept. 29, 2003
9. Amy Dockser Marcus, *Saving Baby Dalton: Doctors, Nurse—And Mom and Dad*, Wall St. J., Oct. 22, 2003
10. Rich Thomaselli, *FDA Holds Hearing For DTC Guidelines; New Rules By Year's End, But McClellan Says DTC Here To Stay*, Advertising Age, Sept. 22, 2003

Press Releases

11. National Mental Health Association, *Barriers to Diagnoses for Common Mental Illnesses Could Prolong Suffering, According to New National Survey* (June 6, 2001)
12. National Mental Health Association, *Depression Survey Reveals Dramatic Change in Public Opinion: Disease or State of Mind?* (July 11, 2001)
13. National Mental Health Association, Michael M. Faenza, President and Chief Executive, *Letter to the Editor*, N.Y. Times, June 25, 2003
14. Remarks by The President, President Calls on Congress to Complete Work on Medicare Bill, Presidential Hall, Dwight D Eisenhower Executive Office Building (Oct. 29, 2003)

Miscellaneous

15. Brief of the United States of America, *In Re Paxil Litigation*, No. CV01-0793 (C.D. Cal. filed Sept. 4, 2002)

16. Letter of Pfizer Inc to Craig Jackson, R.Ph., Director, Division of Occupational and Professional Licensing, Utah Department of Commerce (Apr. 25, 2003), with the following attachments:
 - (a) Medical Board of California, *Internet Prescribing: Ordering Prescriptions Through the Internet? Buyer Beware!*;
 - (b) Federation of State Medical Boards, *Model Guidelines for the Appropriate Use of the Internet in Medical Practice* (adopted Apr. 2002); and
 - (c) Press Release, U.S. Attorney's Office, District of Nevada, *Las Vegas Man Pleads Guilty to Unlawful Distribution of Controlled Substances on the Internet* (Aug. 5, 2003)
17. Dale Glasser, Ph.D., Medical Director, Pfizer Sexual Health, *Untitled Paper* (July 16, 2001)
18. Paul H. Rubin, *The Economics and Impact of Pharmaceutical Promotion*, 3 Economic Realities in Health Care Policy (Dec. 2003)
19. Mike Magee, M.D., "Relationship-Based Health Care in the US, UK, Canada, Germany, S. Africa, and Japan," 2003
20. *Men's Health: A Silent Crisis* (Men's Health Network and Pfizer publication)
21. Pfizer Inc and RxRemedy Information Services, *Impact of DTC Advertising Relative to Patient Compliance* (June 2001)
22. *Racial Differences in Cardiovascular Health: Findings from the National Health and Nutrition Examination Survey (NHANES) III and 1999-2000* (Pfizer Facts publication Aug. 7, 2003)
23. Clifford Thumma, Director, Team Leader, Global Market Analytics, Pfizer Inc. *The Treatment Path*